Message Text

UNCLASSIFIED

PAGE 01 STATE 178173 ORIGIN HEW-06

INFO OCT-01 ARA-14 EA-12 ISO-00 OES-09 COME-00 EB-08 /050 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD: VO APPROVED BY OES/ENP/EN: WJWALSH, III DHEW/PHS/OASH/OI: REVANS EA/J:EFEATHERSTONE(INFO) ARA/CAR:DPIERCE(INFO)

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P 142101Z JUL 78 FM SECSTATE WASHDC TO AMEMBASSY BRIDGETOWN PRIORITY AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 178173

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, BB, JA

SUBJECT: FDA ADVISORY SUPERPOTENT COSMETIC PREPARATION (RECALL F-143-8)

- 1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
 PRODUCT INVOLVED REVLON-REALISTIC PROFESSIONAL PERMANENT
 CREME RELAXER (MILD, 8 OZ. JAR AND 15 OZ. JAR). PRODUCT
 IS A NO BASE PRODUCT. PRODUCT IS ADMINISTERED IN SALONS
 BY PROFESSIONAL HAIRDRESSERS ONLY.
- 2. PRODUCT IDENTIFICATION REVLON-REALISTIC PROFESSIONAL PERMANENT CREME RELAXER, NET WT. 8 OZ AND 15 OZ JAR LABELED IN PART: ,XXX NO BASE FORMULA MILD STRENGTH FOR COLOR TREATED (BOT BLEACHED) SODIUM HYDROXIDE XXX REVLON-REALISTIC PROF. PROD. INC. CINCI, OHIO 45223 MADE IN USA XXX,. NO LABELING IS AVAILABLE FOR 8 OZ. JAR. UNCLASSIFIED

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;ANUFACTURE/RECALLING FIRM: REVLON-REALISTIC PROF. PROD. INC., CINCI, OHIO 45223. RECALLING AND RESPONSIBLE FIRM - REVLON INC., 767 5TH AVENUE, NEW YORK, NY.

3. REASON FOR RECALL - BATCH RECORDS SHOWED A MANUFACT-URING ERROR CAUSED LOT 365 TO CONTAIN 3.2 PERCENT SODIUM HYDROXIDE (NAOH) CONTENT REPORTED UNDER THE VOLUNTARY REGISTRATION OF THIS PRODUCT. THIS EXCESS OF ALKALI CAUSES THE STRAIGHTENING PROCESS TO BE ACCELERATED AND CAN CAUSE BURNS AND PERMANENT HAIR LOSSES.

- 4. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED BY REVLON OF RECALL AND PROCEDURES TO BE FOLLOWED.
- 5. FOREIGN CONSIGNEES AS FOLLOWS:

MGR. CYNTHIA A. CLARKE
R.S. FRENCH AND CO., LTD.
CR. BAXTER RD. AND CHAPMAN ST.
BRIDGETOWN, BARBADOS
WEST INDIES

MR. J.D. BURK
PRESIDENT REVLON PROF. PRODS. DIVISION
2-2-3 MINAMI, AOYAMA
MINATO-KU, TOKYO
JAPAN 107 CHRISTOPHER

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Disposition Remarks:
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TAGS: OGEN, ETRD, EIND, TBIO, BB, JA To: BRIDGETOWN TOKYO

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